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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

MSDI-222/PC765.00

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on January 8, 2009

Signature

Typed or printed
nameBrad A. Schepers

Application Number

10/734,041

Filed

December 11, 2003

First Named Inventor

Lucas Eisermann

Art Unit

3733

Examiner

David C Comstock

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒

attorney or agent of record.

Registration number 45,431☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

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January 8, 2009

Date

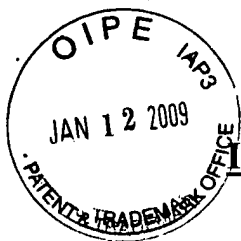
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:)	Before the Examiner
Eisermann et al.)	David C. Comstock
)	
Application Serial No. 10/734,041)	Group Art Unit 3733
)	
Filed December 11, 2003)	Ref. No. MSDI-222/
)	PC765.00
)	
EXPANDABLE INTERVERTEBRAL)	January 8, 2009
IMPLANT)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the final Office Action dated September 5, 2008 and the Advisory Action dated December 9, 2008, please consider the following. A Notice of Appeal and form PTO/SB/33 Pre-Appeal Brief Request for Review are submitted herewith along with the requisite appeal fee under 37 CFR 41.20(b)(1). Additionally, a request for a one-month extension of time including the requisite fee of \$130 is submitted herewith, thereby extending the time period for responding to the final Office Action and the Advisory Action to January 9, 2009. Please charge any additional fees which may be necessary to Deposit Account No. 12-2424, but not to include any payment of issue fees.

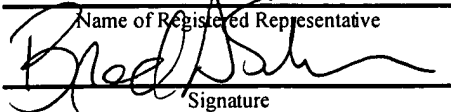
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

January 8, 2009

Date of Deposit

Brad A. Schepers

Name of Registered Representative



Signature

January 8, 2009

Date of Signature

An Advisory Action mailed December 9, 2008 entered Applicant's response to the final Office Action, but indicated that the response did not place the application in condition for allowance. Each of the pending claims 2-29, 33-36, 38-44 and 46-60 have been finally rejected based primarily on a single patent reference; namely, U.S. Patent No. 5,059,193 to Kuslich. The entire basis for rejection of pending independent claims 8, 9, 33, 40, 41, 48 and 50 as being anticipated by Kuslich is set forth in the final Office Action as follows:

Kuslich discloses the claimed invention including using in a surgical procedure a body 12 having axial walls 26 interconnected at their ends and an expansion member 16, 20 co-acting with the walls to expand the body along a transverse axis. The body comprises the axial walls that comprise a rectangular cross-section. The expansion member comprises a component of axial displacement along a longitudinal axis of the device. The inner surfaces of the walls are arcuate or tapered and accordingly comprise a concave recessed area for receiving the expansion member. The walls outwardly deform to from a convex outer curvature. An inner chamber 116 is accessible via openings between the walls. The chamber is filled with bone growth promoting substance. The central portion of the body has a width that is greater than that of the ends. (See page 2; citations omitted). * * * The device of Kuslich comprises the claimed structure. The expansion member is an internal support, positioned within an inner chamber and engaging inner surfaces of the axial walls. Moreover, when the device is expanded, some sliding movement would occur between the expansion member and walls. The expansion member can also be said to be uni-axial because it is actuated along a single axis. (See page 4).

As will be set forth in detail below, the Applicant submits that the summarial description of the invention set forth in the Office Action mischaracterizes and oversimplifies the claimed invention. Additionally, various features recited in each of the pending independent claims 8, 9, 33, 40, 41, 48 and 50 are not clearly disclosed in Kuslich, and the general assertions set forth in the final Office Action do not set forth grounds with sufficient specificity to establish a *prima facie* case of anticipation with regard to independent claims 8, 9, 33, 40, 41, 48 and 50.

As an initial matter, the rejection of each of the independent claims as being anticipated by Kuslich is based, in large part, on the assertion that the inner tubular structure 20 is part of the expander 14. However, Kuslich discloses that the inner tube 20 constitutes a portion of the implant body 12, and not the expander 14. (See col. 3, l. 30-60). Indeed, Kuslich expressly teaches that the inner tubular structure 20 and the outer tubular structure 22 “are joined into a completed assembly 60, as shown in FIG. 13. . . . Inner structure 20 is adhered to the inner surface of outer structure 22 through any suitable mean, such as adhesives or the like.” (See col. 5, l. 66 to col. 6, l. 3; emphasis added). In summary, Kuslich discloses that the inner and outer tubes 20, 22 are joined together to form an integrated/composite implant body 12. (See col. 4, ll. 59-64). Accordingly, the assertion that the inner tube 20 is part of the expander 14 is incorrect.

Furthermore, the implant expander 14 does not engage central portions of the axial walls of the implant body 12, but instead includes end caps 18, 32 that engage the end rings 23 of the implant body 12, and which are drawn together to exert an axial compressive force onto the end rings 23 to expand the implant body 12. Indeed, no portion of the expander 14 is in any way engaged with the axially-extending ribs of the implant body 12 at a central location intermediate the end rings 23. Likewise, no portion of the expander 14 extends transversely between and engages central/mid-portions of the axially-extending ribs to expand the implant body 12. (See Figs. 2, 2B and 24). Moreover, even assuming arguendo that the inner ribs 28 could somehow be construed to constitute a portion of the expander 14, the inner ribs 28 do not extend transversely between and engage central portions of the outer ribs 26 to expand the implant body 12, as recited in each of the pending independent claims. Instead, the inner ribs 28 extend axially along the outer ribs 26, and not transversely between central portions of the outer ribs 26.

Moreover, independent claims 8, 9, 40, 41 and 48 each recite that the expansion member comprises “an internal support member positioned within a central region of said inner chamber and having a height extending transversely between and engaging opposing inner surfaces of said central portions of said first and second axial walls”. However, the Kuslich implant 10 does not include any structure or element that could reasonably be construed as an internal support member positioned within a central region of the implant body 12 and having a height extending transversely between and engaging opposing inner surfaces of central portions of the ribs 26, 28. Indeed, the only structure positioned within the central region of the interior of the implant body 12 is the tie rod 16 of the expander 14. However, the tie rod 16 clearly does not have a height that engages opposing inner surfaces of the central portions of the axially-extending ribs 26, 28. Indeed, the transverse height of the tie rod 16 is considerably less than the distance between the ribs 26, 28, and does not in any way engage central portions of the ribs 26, 28. Furthermore, even if the inner ribs 28 could somehow be construed to constitute a portion of the expander 14, the transverse height of the inner ribs 28 is considerably less than the distance between the outer ribs 26, and neither of the inner ribs 28 have a height extending transversely between and engaging opposing inner surfaces of each of the outer ribs 26 to provide an internal support. The Applicant further notes that the subject application discloses that “positioning of the expansion pin 24 within the center compartment 90c of the inner chamber 40 provides additional support and rigidity . . . to resist compression loads from the vertebral bodies V_U , V_L , particularly near the central portion 22c of the fusion cage 22 which is otherwise devoid of internal support

members.” (See paragraph 56). However, the Kuslich implant fails to provide any type of transverse internal support member at a central region of the implant interior that is engaged between central portions of the axial ribs. Moreover, the Office Action does not set forth any grounds or rationale as to how Kuslich satisfies the above-discussed features. Indeed, the Office Action does not even mention or in any way refer to the term “height”, much less how any portion of the expander 14 has “a height extending transversely between and engaging opposing inner surfaces” of central portions of the ribs 26, 28. Accordingly, a *prima facie* case of anticipation has not been established with regard to independent claims 8, 9, 40, 41 and 48.

Additionally, independent claim 8 recites that the expansion member cooperates with the axial walls to “uni-axially expand said body along said transverse axis”, independent claim 41 recites that the expansion member cooperates with the axial walls to “outwardly deform and uni-axially expand said first and second axial walls along said transverse axis”, and independent claim 48 similarly recites that expansion of the body comprises “outward deformation and uni-axial expansion of said first and second axial walls along said transverse axis”. Figures 6 and 7 of the subject application clearly illustrate the expansion member 24 cooperating with the axial walls 30, 32 to uni-axially expand the implant body 22 along a single transverse axis T. However, the implant body 12 of Kuslich is expanded along multiple axes to provide a spherical-shaped expanded implant configuration. (See Fig. 1). Since the implant body 12 expands along multiple axes to provide the spherical-shaped configuration, the implant body can not reasonably be said to uni-axially expand along a single transverse axis, as recited in independent claims 8, 41 and 48. Nevertheless, the Office Action asserts that “the expansion member can also be said to be uni-axial because it is actuated along a single axis. (See page 4; emphasis added). However, independent claims 8, 41 and 48 specifically recite that the first and second axial walls are uni-axially expanded along the transverse axis. Even if the Kuslich implant body 12 could somehow be construed as uni-axially actuated along a single axis, the implant body is clearly expanded along multiple axes to provide a spherical-shaped expanded implant configuration shown in Fig. 1. Accordingly, a *prima facie* case of anticipation has not been established with regard to independent claims 8, 41 and 48 for these additional reasons as well.

Independent claims 9 and 40 also recite “said expansion member slidably engaged along opposing inner surfaces of said first and second axial walls during said axial displacement”, and independent claim 50 recites “slidably engaging the expansion member along opposing inner surfaces of the first and second axial walls in a direction along the longitudinal axis”. However,

the implant body 12 of Kuslich is not expanded by slidably engaging any portion of the expander 14 axially along the ribs 26, 28. Instead, the end caps 18, 32 are compressed against the end rings 23 to expand the implant body 12, and no portion of the expander 14 is in any way slidably engaged with the ribs 26, 28 to expand the implant body 12. Furthermore, even assuming arguendo that the inner ribs 28 are construed to constitute a portion of the expander 14, as set forth above, Kuslich discloses that the inner and outer tubular structures 20, 22 are joined together to form an integrated/composite implant body 12. The assertion set forth in the Office Action that “when the device is expanded, some sliding movement would occur between the expansion member and walls” is incorrect. (See page 4). Indeed, since Kuslich specifically discloses that the inner and outer tubes 20, 22 are joined together to form an integrated implant body 12, there would be no sliding engagement of the inner ribs 28 along the outer ribs 26. Accordingly, a *prima facie* case of anticipation has not been established with regard to independent claims 9, 40 and 50 for these reasons as well.

Independent claim 33 further recites that “said axial walls and said transverse end walls defining generally flat and planar upper and lower vertebral bearing surfaces extending substantially entirely across said implant width”. With regard to Kuslich, the implant body 12 has a cylindrical configuration in the initial state and a spherical configuration when expanded. Even assuming arguendo that a single/individual rib 26 could be construed to have a generally flat and planar upper/lower bearing surface, the Applicant notes that the entire implant body 12 must define generally flat and planar upper and lower vertebral bearing surfaces extending substantially entirely across said implant width, as recited in independent claim 33. The implant body 12 of Kuslich clearly does not satisfy these features. Indeed, to find otherwise would entirely disregard and ignore the cylindrical and spherical configurations of the implant body in the initial and expanded states, respectively. Accordingly, a *prima facie* case of anticipation has not been established with regard to independent claim 33 for this additional reason.

In summary, independent claims 8, 9, 33, 40, 41, 48 and 50 recite various features that are not disclosed by Kuslich, and the brief and summarial grounds of rejection set forth in the final Office Action fail to establish a *prima facie* case of anticipation with regard to these claims.

Respectfully submitted,

By: 
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